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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,027	07/16/2003	Nai-Kong V. Cheung	#639-B-PCT-US	2089

7590 03/06/2006

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EXAMINER	
JOHNSEN, JASON H	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,027	CHEUNG, NAI-KONG V.	
	Examiner	Art Unit	
	Jason H. Johnsen	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *149-188* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *149-188* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *N/A* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01/11/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 149-166 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 89-107 of copending Application No. 11218044. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 149-160, 163-184, 186, and 188 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dorothee Herlyn (US 5,130,127), James et al (US 5,849,720), Yan et al. (" Beta-glucan, a "specific" biologic response modifier that uses antibodies to target tumors for cytotoxic recognition by leukocyte complement receptor Type 3," Journal of immunology, 1999, Vol. 163, pp. 3045-3052), Dante J. Marciani (US 6,573,245), Cheever et al. (US 6,664,370), Chu et al. (Pub No. 2004/0109857), and Lane et al. (Pub No. 2003/0180254).

A. Claim 149 teaches a composition for achieving a synergistic therapeutic effect in a mammal in need thereof, comprising: a) a glucan comprising a backbone having 1,3-beta linkages; and b) an antibody administered to a mammal and is effective against cancer or tumor cells. Claim 150 further limits claim 149 by requiring the antibody to be a monoclonal antibody or a tumor-binding antibody. Claim 151 further limits claim 149 by requiring the antibody to be capable of activating complement. Claim 152 further limits claim 149 by requiring the antibody to be capable of activating the antibody dependent cell-mediated cytotoxicity. Claim 153 further limits claim 149 by requiring the antibody to be directed to HER-1or a ganglioside. Claim 154

further limits claim 149 by requiring the ganglioside to be GD2 or GD3. Claim 155 further limits claim 149 by requiring the antigen to be CD20 or CD22 or HER-2/neu or CD25. Claim 156 further limits claim 149 by requiring the cancer to be a specific cancer listed therein. Claim 157 further limits claim 149 by requiring the composition be administered with a pharmaceutically acceptable carrier. Claim 158 further limits claim 149 by requiring a high molecular weight glucan or requiring the molecular weight of the glucan range from 250,000 to 450,000 daltons. Claim 159 further limits claim 149 by requiring the glucan be derived from barley, oat, wheat or moss.

B. Dorothee Herlyn teaches a method of treating human tumors in vivo by providing a 1,3 backboned glucan followed by treatment with anti-tumor monoclonal antibodies (see abstract, column 1, lines 44-65; column 2, lines 25-30). Dorothee Herlyn teaches a monoclonal tumor-binding antibody against cancer (column 1, lines 11-55), which is capable of activating complement (column 3, lines 40-45). Dorothee Herlyn teaches an antibody capable of activating the antibody dependent cell-mediated cytotoxicity (column 2, lines 25-30). Additionally, Dorothee Herlyn teaches the cancer to be melanoma, pancreatic cancer or colon cancer (column 3, lines 55-57, claims 10 and 11), and the glucan to be high molecular weight between 400,000 and 800,00 daltons (column 2, lines 38-40). Dorothee Herlyn does not explicitly teach a composition comprising a glucan and an antibody, nor does she teach the specific identities of the antibodies to be HER-1, a ganglioside, CD20, CD22 or CD25.

C. Dante J. Marciani teaches the antibody directed at HER-1 (column 12, line 54).

D. Yan et al. teach the antibody directed to a ganglioside (page 12, middle paragraph, and page 14, last paragraph), and specifically, to ganglioside GD2 (page 12, middle paragraph).

E. Chu et al. teach the antigen to be CD20 (page 15, paragraph 96 and table 4).

F. Cheever et al. teach the antigen to be HER-2/neu (column 14, lines 47-57).

G. Lane et al. teach the antigen to be CD25 (page 2, paragraph 25, and page 12, paragraph 133).

H. James et al. teach a composition comprising an effective amount of orally administered glucan that is capable of enhancing efficacy of antibodies(see column 4, lines 54-64), but not monoclonal antibodies. James et al. teach the use of said composition paired with a pharmaceutically acceptable carrier and the glucan being derived from yeast, bacteria, fungi, and plants (column 1, lines 13-15). James et al. teach the glucan to be a high molecular weight ranging from 10,000 to 500,000 daltons (column 4, lines 23-25), which is stable to heat treatment (see Examples 1 and 2, column 5 and 6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the above taught composition in an effective amount as taught by the applicant having the above-cited references before him. It is well known in the art that glucan works by activating the immune system in response to a myriad of factors, including many types of foreign cells and intigens--viruses, bacteria, and various types of cancer. Specifically, glucan mimics the natural physiologic response to an infectious challenge by enhancing the balanced, endogenous release of cytokines (James et al.). By considering the teaching of Dorothee Herlyn, it would lead one skilled in the art to have a reasonable expectation of success in combining the explicit method of treating various cancer tumors by combining various monoclonal antibodies with glucan to enhance the synergistic and therapeutic effect of the antibody as taught by Dorothee Herlyn with Marciani et al, Yan et al., Chu et al., Cheever et

al,Lane et al., and James et al., to develop a composition to treat infectious and autoimmune diseases, including enhancing efficacy of antibodies against many types of cancer. Dorothee Herlyn teaches this very method explicitly. The composition as taught by Applicants claim 149 is an inherent property of the method of use as taught by Herlyn. One skilled in the art would be motivated to combine these teachings to obtain a less evasive, more convenient cancer fighting regiment that included oral administration of tumor fighting agents, and thus overcome what was once a significant impediment in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 149-188 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling a composition for treating some types of cancers, mainly a neuroblastoma, comprising administering an effective amount of beta glucan and specific monoclonal antibody, 3F8, it does not reasonably provide enablement for all types of cancers and antibodies generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation.

These claims sets forth the **treatment of cancer or tumor cells** generally, by synergistically enhancing the effects of antibodies generally or more narrowly, but still too broad, species of antibodies, as well as treatment of a very broad range of specific cancers as found in claims 156 and 180. However, there never has been a compound capable of treating

cancer generally. There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. The treatment of cancer is highly unpredictable due to the differing forms of cancerous cells, their location, their potential for metastases, the fact that cancer therapeutics is palliative rather than curative and that cancer treatment readily harms normal tissues (see Katzung pp. 881-882). Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers or tumor cells generally by enhancing the effectiveness of antibodies generally or the wherein the antibody is capable of activating complement or dependent cell-mediated cytotoxicity; evidence that the level of skill in this art is low relative to the difficulty of such a task. There are enumerable antibodies capable of doing these activities, as well as antibodies directed to specific receptors or directed to gangliosides generally. Several specific gangliosides have been identified: Applicant's expiremental data is drawn to a specific monoclonal antibody, 3F8, which targets a specific ganglioside, GD2, in a specific cancer, neuroblastoma. Applicant has not shown a sufficient nexis between treating cancers broadly, or

treating the long list of cancers found in claims 156 and 180, using antibodies broadly or even antibodies directed to certain receptors or gangliosides.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006. Thus, the enablement rejection is proper.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 155 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons:

Claim 155 is indefinite because it refers to the "antigen" of claim 150, when in fact there is no antigen mentioned in claim 150. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**. The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jason H. Johnsen
Patent Examiner
Art Unit 1624

James O. Wilson
Supervisory Patent Examiner
Art Unit 1624